Recall -- Firm Press Release

Medtronic Initiates Voluntary Field Actions for Selected Heparin-Coated Products Used During Cardiopulmonary Bypass

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FOR IMMEDIATE RELEASE -- MINNEAPOLIS – May 7, 2008 – Medtronic, Inc. today announced that it is initiating a voluntary and precautionary recall of selected products featuring the Carmeda BioActive surface. The affected devices are disposable products used during cardiopulmonary bypass (CPB) for heart surgeries. Affected products include blood oxygenators, reservoirs, pumps, cannulae, and tubing packs. This action is being taken subsequent to the U.S. Food and Drug Administration's April 8, 2008 recommendation to device manufacturers that heparin supplies be checked with newly-developed tests, and that affected products be evaluated for possible field corrective action.

Limited lots of Carmeda-coated products were manufactured with heparin found to have been contaminated with oversulfated chondroitin sulfate (OSCS). The patient risk associated with the presence of OSCS in heparin-coated medical devices is not known at this time. However, the U.S. Food and Drug Administration has received reports of serious injury and death in patients who have been administered injectable heparin products containing high levels of OSCS.

Medtronic has not received reports of any OSCS-related adverse events arising from the use of Carmeda CPB products. It is unclear, however, if exposure to Carmeda-coated medical devices, made with comparatively small amounts of heparin, could cause adverse events similar to those observed with injectable heparin formulations. As a result, Medtronic has initiated a precautionary recall of affected Carmeda products.

In a separate action, Medtronic is advising customers that selected lots of Trillium-coated products were also manufactured with heparin containing OSCS. Trillium is another biosurface used on CPB products.

The amount of heparin on the product is significantly lower than that contained on the Carmeda product. Medtronic's ultimate goal is to remove contaminated products from the market. However, based on the current data, the benefit of using the affected products outweighs any potential risk to patients. Since the maximum possible patient exposure to heparin from Trillium is extremely low, customers can continue to use the affected Trillium products until a replacement is available.

The above actions are being made with the knowledge of the U.S. Food and Drug Administration. Patients with questions should talk to their physician. Physicians or Pefusionists with medical questions related to Medtronic therapies should contact Medtronic at 1-800-638 0218, Monday – Friday, 8:00 a.m. to 5:00 p. m. CDT

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